

REMARKS

Applicant has carefully reviewed and considered the Office Action mailed on May 4, 2004, and the references cited therewith. To expedite the prosecution of this case, claim 52 has been amended as suggested by the Examiner to include the subject matter of claim 2 and to include a definition of "sufficient amount" (from page 15, third paragraph, of the specification) and an explanation of the polysaccharides's viscosity (from page 12 of the specification). Claims 1, 54-57, 97 and 98 have been amended to depend from claim 52. Claims 2-18, 22-51, 53 and 75-96 have been withdrawn without prejudice. New claim 99 has been added to further delineate the subject matter to which Applicant is entitled. Support for the subject matter of claim 99 can be found in the specification at page 21. As a result, Claims 1, 19-21, 52, 54-74, 97, 98 and 99 are now pending in this application. Applicant submits that these amendments do not add new matter.

In an e-mail dated September 6, 2004, the Examiner stated that claims with such amendments would be allowable. Applicant therefore believes the pending claims should be allowed and allowance of the pending claims is earnestly solicited.

Telephone Interview Summary

Applicants would like to thank Examiner Page for the courtesy extended during the telephonic interview on August 19, 2004. Inventor Daniel Gallaher, Applicants' representative Kristina Sticha and Applicants' attorney Robin A. Chadwick participated in the interview with Examiner Page.

The pending claims and cited art were discussed during the interview. In response to allegations by the Examiner that the claimed decrease in percentage of body fat was inherently disclosed by the prior art relating to weight loss, Applicants pointed out that the claimed subject matter would not necessarily follow from the disclosures of the prior art and that none of the prior art references enable one of skill in the art to make and use the invention. The Examiner proposed certain claim amendments and to expedite the prosecution of this case, and agreed to review a proposed set of claims. Applicant's attorney, Robin A. Chadwick, sent the Examiner a proposed set of claims on Aug. 27, 2004. On Sep. 6, 2004, the Examiner responded with an e-mail suggesting that of the following subject matter was inserted into claim 52, then claim 52

would be allowable: the viscosity range disclosed on page 12, the amount of polysaccharide recited in the third paragraph at page 15 and the subject matter claim 2.

This account is believed to be a complete and accurate summary of the interview as required by 37 C.F.R. § 1.133. If the Examiner believes that this summary is inaccurate or incomplete, Applicant respectfully requests that the Examiner point out any deficiencies in his next communication so that Applicant can amend or supplement the interview summary.

§102 Rejections of the Claims

Claims 1, 6, 9, 22-24, 36 and 37 were rejected under 35 U.S.C. § 102(b) as being anticipated by WO 98/50398 A1 by Pinto. According to the Examiner, the Pinto et al. reference discloses compositions that include a beta-glucan that slows the rate of gastric emptying, reduces the rate of carbohydrate absorption and absorbs and eliminates fats in the gut (citing Pinto at page 1 lines 22-26 and page 6, lines 15-19). The Examiner asserts that Pinto et al. anticipates all elements of Claims 1, 6, 9, 22-24, 36 and 37.

Claims 1-6, 9, 13, 24 and 27 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 6,143,731 to Jamas et al. According to the Examiner, the Jamas et al. reference discloses beta-glucan compositions administered to promote weight loss or reduce weight gain is that amount necessary to aid digestion, speed transit time of undigested food and insure the proper working of peristaltic muscles (citing Jamas at column 6, line to column 7, line 3). The Examiner asserts that Jamas et al. anticipates all aspects of Claims 1-6, 9, 13 and 24.

Claims 1, 6 and 22 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Publication 2003/0039708 A1 to Fleischner. According to the Examiner, the Fleischner reference teaches that the disclosed compositions increase fat loss as well as reduce weight (citing Fleischer, paragraph 0006). The Examiner asserts that Fleischner anticipates all aspects of Claims 1, 6 and 22.

Claim 1 is now dependent upon claim 52. Claim 52 of the present invention is directed to a method of reducing the level of leptin in the bloodstream of a mammal comprising administering a sufficient amount of viscous, water-soluble, non-nutritive, non-starch, indigestible polysaccharide to the mammal for a time sufficient to reduce the level of leptin in the bloodstream of the mammal, wherein the sufficient amount of the polysaccharide is about 2% to about 20% of total polysaccharide in the mammal's diet, the polysaccharide is a polymer of

monosaccharides substantially connected by beta (β) glycosidic linkages, and a 2% aqueous solution of the polysaccharide has a viscosity of about 50 cps to about 200,000 cps.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989). To constitute anticipation, the claimed subject matter must be identically disclosed in the prior art. *In re Arkley*, 172 U.S.P.Q. 524 at 526 (C.C.P.A. 1972). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 101 (Fed. Cir. 1991). To overcome the defense of anticipation, "it is only necessary for the patentee to show some tangible difference between the invention and the prior art." *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172, (9th Cir. 1981).

Moreover, an anticipation rejection that is based on inherency must be supported by factual and technical grounds establishing that the inherent feature must flow as a necessary conclusion, not simply as a possible conclusion, from the teaching of the cited art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990); *In re Oelrich*, 666 F.2d 578, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

Applicant submits that none of the cited references provide any teaching on leptin whatsoever and requests withdrawal of each of these rejections under 35 U.S.C. § 102.

Applicant further traverses these rejections as follows, insofar as the rejections relate to reduction in percent body fat. During the telephone interview on August 19, 2004, the Examiner asserted that the cited references inherently anticipate the present claims. Applicant submits that a disclosure that teaches loss of body weight cannot inherently disclose reduction in percentage body fat because, to be an inherent disclosure, reduction in percentage body fat must flow as a necessary conclusion, not simply as a possible conclusion, from the teaching of the disclosure. When a mammal loses weight there is frequently no change in the percentage of fat in the mammal because muscle, bone or fluids may be lost instead of, or in addition to, fat. For example, people often lose bone mass or bone calcium when they diet (however, this does not

happen with the present methods as shown in Table 3, page 22, of Applicant's application). Moreover, after traditional diets, people frequently re-gain lost fluids or put on more weight (fat) than was lost. In these situations, no real change in body composition was achieved and data relating to weight loss is temporary and misleading. Hence, reduction in percentage body fat does not flow as a necessary conclusion from the teaching of the disclosures cited by the Examiner on weight loss.

Moreover, Applicant submits that all of the prior art references cited by the Examiner lack enablement even for reducing body weight, much less reducing percentage of body fat. The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Foundation for Medical and Education Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003). Applicant submits that the Pinto, Jamas et al. and Fleischner et al. references do not enable a method of reducing the percentage of body fat in a mammal by administering a sufficient amount of viscous, water-soluble, non-nutritive, non-starch, indigestible polysaccharide to the mammal. Neither of the Pinto et al. or the Fleischner et al. references provides any data whatsoever illustrating that such a polysaccharide can reduce the percentage of body fat in a mammal or what amounts of such a polysaccharide would be effective for reducing the percentage of body fat in a mammal. Similarly, the Jamas et al. reference lacks enablement because it does not address reduction in percentage body fat and provides confusing, contradictory data on which type and what amount of polysaccharides might be used for achieving weight loss (while providing no mention of reducing percentage of body fat). Hence, as described in more detail below, none of the Pinto, Fleischner or Jamas et al. references explicitly or inherently discloses the invention or provides sufficient enablement for one of skill in the art to practice the invention.

WO 98/50398 A1 by Pinto is limited to a disclosure of a process for producing β -glucans. While Pinto makes a few gratuitous comments about β -glucans being beneficial for the control of obesity, Pinto provides no data showing such an effect and does not disclose that the β -glucans so produced are useful for reducing the percentage of body fat in a mammal. As explained by inventor Gallaher during the Interview on August 19, 2004, the comments by Pinto that the Examiner cited are actually false – β -glucans do not decrease fat absorption or increase

elimination of fat from the gut. No evidence exists that the formulations provided by Pinto would actually reduce or eliminate fat absorption at its source. Instead, Pinto simply states that the β -glucans have “improved properties” that relate to having better resistance to enzymatic degradation. While Pinto attempts to remove starch from the β -glucans employed in his compositions (see page 8, lines 24-26), there is no disclosure, tests or data showing that the β -glucans produced by Pinto are non-nutritive or indigestible. Nor does Pinto disclose that the β -glucans can give rise to increased intestinal viscosity, which might be one indication that the Pinto β -glucans are indigestible. Given the complete lack of data in Pinto, one of skill in the art could not necessarily conclude that Pinto discloses the claimed compositions or that the compositions that are disclosed can give rise to reduction in body fat. Nor would Pinto et al. enable one of skill to formulate a composition containing the claimed polysaccharide in an amount sufficient to reduce the percentage of body fat. Therefore, WO 98/50398 A1 by Pinto does not anticipate the subject matter of claims 1, 6, 9, 22-24, 36 and 37.

Like the Pinto, U.S. Publication 2003/0039708 A1 to Fleischner provides no data whatsoever illustrating that a sufficient amount of viscous, water-soluble, non-nutritive, non-starch, indigestible polysaccharide can reduce the percentage of body fat in a mammal or what amounts of such a polysaccharide would be effective for reducing the percentage of body fat in a mammal. Fleischner are limited to compositions containing many components, including chromium, vanadium, glucomannan, green tea extract, forskolin, sodium carboxymethyl cellulose and various excipients. Even if data were provided by Fleischner, the composition provided by Fleischner is so complex that there could be no disclosure that a polysaccharide was responsible for weight loss, let alone reduction in body fat. Moreover, there is no disclosure that any of these components is actually a viscous, water-soluble, non-nutritive, non-starch, indigestible polysaccharide.

The disclosure of Fleischner is confusing and contradictory. For example, according to Fleischner, one study indicates that administration of a polysaccharide (glucomannan) leads to weight loss while other studies apparently do not show such weight loss (see Fleischner at paragraph 0025). Such confusion is not an explicit or inherent disclosure that a polysaccharide of any variety can be used for reducing body fat. The ambiguous information provided by Fleischner does not constitute sufficient factual and technical grounds to establish that the inherent feature (reduced body fat) must flow as a necessary conclusion from the Fleischner

disclosure. Thus, the claimed subject matter is not identically disclosed either explicitly or inherently in U.S. Publication 2003/0039708 A1 to Fleischner, and this publication does not anticipate the claimed invention.

Jamas et al. also provide no data whatsoever on whether a polysaccharide of any type can reduce body fat. Like Fleischner, U.S. Patent 6,143,731 to Jamas et al. also provides confusing information on whether or not a polysaccharide (β -glucan) can influence body weight (not to mention body fat). The confusing data provided by Jamas et al. include disclosure that oat bran actually causes weight gain (see Jamas et al. Tables 11 and 12). Similarly, Jamas et al. does not describe whether the oat bran or whole glucan apparently employed is actually a viscous, water soluble polysaccharide, which may be why the data provided by Jamas et al. is confusing and contradictory. Such a confusing disclosure is not an explicit or inherent disclosure of reducing body fat by administering a viscous, water soluble polysaccharide. Nor is it an enabling disclosure of a sufficient amount of a viscous, water soluble polysaccharide that can reduce the percentage of body fat in a mammal. Hence, even if reduction of body weight were equivalent to reduction of body fat, the ambiguous data and uncertain compositions of Jamas et al. do not constitute sufficient factual and technical grounds to establish that the inherent feature (viscous water soluble polysaccharide giving rise to reduced body fat in a mammal) must flow as a necessary conclusion.

Hence, the claimed subject matter is not identically disclosed in U.S. Patent 6,143,731 to Jamas et al. either explicitly or inherently and the claims are not anticipated by U.S. Patent 6,143,731 to Jamas et al.

Accordingly, none of the claims are anticipated by WO 98/50398 A1 by Pinto, U.S. Patent 6,143,731 to Jamas et al., U.S. Publication 2003/0039708 A1 to Fleischner, or U.S. Publication 2003/0019334 A1 by Portman. Applicants respectfully request withdrawal of these rejections of the claims under 35 U.S.C. §§ 102(b) and 102(e).

§103 Rejection of the Claims

Claims 1-37 and 52-74 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 6,143,731 to Jamas et al. in view of WO 98/50398 A1 by Pinto or U.S. Publication 2003/0019334 A1 by Portman. According to the Examiner, in addition to the points made in the discussion of the 102 rejections above, Jamas et al. further teaches that the beta-

glucan containing composition can be included as part of a complete nutritional food (citing column 7, line 13). While Jamas et al. does not enumerate specific examples of food items, Pinto discloses that beta-glucan containing food can be developed into cereals, snacks, pasta and yogurt. Moreover, according to the Examiner, Portman teaches a nutritional composition comprising soluble fibers such as hydroxypropylmethylcellulose (citing page 4, paragraph 0059) and weight loss over a period of 6 weeks.

Claims 38-51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Publication 2003/0019334 A1 by Portman in view of Bahram et al., J. Nutrition 27: 463 (1997). According to the Examiner, in addition to the points made in the discussion of the 102(e) rejections above, Portman discloses weight loss due a feeling of satiety over a period of six weeks.

Claim 1 is now dependent upon claim 52. Claim 52 of the present invention is directed to a method of reducing the level of leptin in the bloodstream of a mammal comprising administering a sufficient amount of viscous, water-soluble, non-nutritive, non-starch, indigestible polysaccharide to the mammal for a time sufficient to reduce the level of leptin in the bloodstream of the mammal, wherein the sufficient amount of the polysaccharide is about 2% to about 20% of total polysaccharide in the mammal's diet, the polysaccharide is a polymer of monosaccharides substantially connected by beta (β) glycosidic linkages, and a 2% aqueous solution of the polysaccharide has a viscosity of about 50 cps to about 200,000 cps.

The test for obviousness under § 103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985). The Examiner must also recognize and consider not only the similarities but also the critical differences between the claimed invention and the prior art. *In re Bond*, 910 F.2d 831, 834, 15 U.S.P.Q.2d (BNA) 1566, 1568 (Fed. Cir. 1990), *reh'g denied*, 1990 U.S. App. LEXIS 19971 (Fed. Cir. 1990). Hindsight must also be avoided. *Id.* The Examiner cannot use the Appellant's structure as a "template" and simply select elements from the references to reconstruct the claimed invention. *In re Gorman*, 933 F.2d 982, 987, 18 U.S.P.Q.2d (BNA) 1885, 1888 (Fed. Cir. 1991).

Applicant submits that none of the cited references teaches methods of reducing the percentage of body fat in a mammal that involve administering a sufficient amount of viscous, water-soluble, non-nutritive, non-starch, indigestible polysaccharide to the mammal. Contrary to the Examiner's allegations, U.S. Patent 6,143,731 to Jamas et al. do not provide a teaching on whether a β -glucan supplement can lead to weight loss, let alone reduction in percent body fat. The data provided in the Jamas et al. disclosure are confusing and contradictory indicating that Jamas et al. have not identified what type of fiber can facilitate loss of weight or reduction in body fat. In particular, Table 12 of the Jamas et al. reference shows that oat bran with 43% fiber does not reduce weight gain. See especially, Jamas et al. at col. 16, lines 27-28. Table 11 in the Jamas et al. reference shows that oat bran actually causes a weight gain. Hence, Jamas et al. is limited to disclosure of complex mixtures of fibers that have contradictory effects on weight loss. As such, the Jamas et al. reference does not disclose or teach the present methods of reducing body fat by administering a viscous, water-soluble polysaccharide to a mammal.

None of the other references cited by the Examiner cure the defects present in the Jamas et al. reference. In particular, Pinto is limited to a disclosure of a process for producing β -glucans and provides no data, no teaching and no disclosure on what property or component of β -glucan can reduce percent body fat. Portman is limited to disclosure of a composition for enhancing and extending satiety that includes protein, casienmacropeptide or glycomacropeptide, long chain fatty acids, and soluble and/or insoluble fibers, and also provides no disclosure or teaching on whether such a composition can reduce leptin or body fat, or what component of this complex mixture can reduce leptin or body fat.

The Examiner has cited Andrico et al. (Human Reproduction 17(8): 2043 (Aug. 2002)) as evidence that a positive correlation exists between leptin and body weight. Applicant submits that the Andrico et al. reference (published Aug. 2002) is not prior art to the present application (filed Dec. 19, 2001). Hence, the teachings of Andrico are irrelevant to the patentability of the present invention.

Moreover, as described above, reduction of fat mass is distinct from reduction in body weight. One of skill in the art cannot know whether a composition can change fat mass without testing it. For example, as shown by the Pawlak article cited in response to the previous Office Action, a diet that is high in carbohydrate leads to higher fat mass than a diet that is low in carbohydrate, while leading to no change in body weight. J. Nutr. 131:99-104 (2001). One of

skill in the art could not have known which diet would reduce fat mass because conventional wisdom teaches that diets low in fat (and consequently usually high in carbohydrate) are better for losing weight. Hence, one of skill in the art would not derive from the confused teachings of Jamas, Pinto and Portman on weight loss that administration of viscous, water-soluble, non-nutritive, non-starch, indigestible polysaccharides can reduce leptin levels or the percentage of body fat in a mammal.

Applicant submits that the present invention is non-obvious in view of the contradictory teachings of Jamas et al. and the failure of Jamas, Portman and Pinto to disclose reduction of leptin levels and what type of fiber can actually reduce body fat. Applicant requests withdrawal of the rejection of claims 1-37 and 52-74 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 6,143,731 to Jamas et al. in view of WO 98/50398 A1 by Pinto or U.S. Publication 2003/0019334 A1 by Portman.

The Examiner has further rejected claims 38-51 under 35 USC § 103(a) as being unpatentable over U.S. Publication 2003/0019334 A1 by Portman in view of Bahram et al., J. Nutrition 27: 463 (1997). According to the Examiner, in addition to the points made in the discussion of the 102(e) rejections above, Portman discloses weight loss due a feeling of satiety over a period of six weeks.

Claims 38-51 have been withdrawn without prejudice to its prosecution at a later date. Applicant respectfully requests withdrawal of this rejection under 35 U.S.C. § 103(a).

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (516-795-6820) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date October 4, 2004

By _____

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 4th day of August 2004.

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